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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,933	12/30/2003	David J. Parins	1001.1676101	1930
28075 7590 05/29/2007 CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420			EXAMINER TOWA, RENE T	
			ART UNIT 3736	PAPER NUMBER
			MAIL DATE 05/29/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/748,933

Applicant(s)

PARINS ET AL.

Examiner

Rene Towa

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2007.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-15,17-22,59 and 60 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1,3-15,17-22,59 and 60 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office action is responsive to an amendment filed January 5, 2007. Claims 1, 3-15, 17-22 and 59-60 are pending. Claims 2 and 16 have been cancelled. No new claim has been added. Claims 1 and 14 have been amended.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1, 3-7, 12-15, 17, 21-22 and 59-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richardson et al. (US Patent No. 6,673,025).

In regards to claim 1, Richardson et al. discloses a guidewire 140, comprising:
a core member 141 having a proximal end and a distal end;
a tubular member 156 having a proximal end and a distal end, the tubular member 156 disposed about and connected to the distal end of the core member 141, the distal end of the tubular member 156 extending distally beyond the distal end of the core member 141; and

a coil member 151 connected to the tubular member 156 (see fig. 20).

In regards to claim 3, Richardson et al. discloses a guidewire wherein the proximal end of the coil member 151 is positioned distal of the distal end of the core member 141 (see fig. 20).

In regards to claim 4, Richardson et al. discloses a guidewire wherein the proximal end of the tubular member 156 fits over the distal end of the core member 141 (see fig. 20).

In regards to claim 5, Richardson et al. discloses a guidewire wherein the proximal end of the coil member fits over the distal end of the tubular member (see fig. 20).

In regards to claim 6, Richardson et al. discloses a guidewire further including a polymer sheath 157 disposed about the coil member 151, the tubular member 156, and at least a portion of the core member 141 (see fig. 20).

In regards to claim 7, Richardson et al. discloses a guidewire wherein the polymer sheath 157 is disposed over all of the core member 141 (see fig. 20).

In regards to claim 12, Richardson et al. discloses a guidewire wherein the tubular member 156 has a hemispherical cross section (see fig. 20).

In regards to claim 13, Richardson et al. discloses a guidewire wherein the tubular member 156 has a circular cross section (see fig. 20).

In regards to claim 14, Richardson et al. discloses a guidewire comprising:
a core member 141 including a proximal portion having a proximal end and a distal portion having a distal end; and

a distal assembly (151, 156) including a tubular member 156 having an inner surface adapted for connection to the distal portion of the core member 141, and an outer surface, and a coil member 151 connected to the tubular member 156;

wherein the distal assembly (151, 156) is connected to the distal portion of the core member 141 such that a portion of the distal assembly extends distally beyond the distal end of the core member 141 (see fig. 20).

In regards to claim 15, Richardson et al. discloses a guidewire wherein the distal assembly is connected to the distal portion of the core member 141 such that a portion of the tubular member 156 extends distally beyond the distal end of the core member 141 (see fig. 20).

In regards to claim 17, Richardson et al. discloses a guidewire further including a polymer sheath disposed about the coil member 151, the tubular member 156, and at least a portion of the core member 141 (see fig. 20).

In regards to claim 21, Richardson et al. discloses a guidewire wherein the tubular member 156 has a hemispherical cross section (see fig. 20).

In regards to claim 22, Richardson et al. discloses a guidewire wherein the tubular member 156 has a circular cross section (see fig. 20).

In regards to claim 59, Richardson et al. discloses a medical device comprising:
an elongated shaft 141 including a proximal portion having a proximal end and a distal portion having a distal end; and

a distal assembly including a tubular member 156 and a ribbon or wire 151 connected to and extending distally of the tubular member 156; wherein the distal assembly is connected to the distal portion of the elongated shaft 141 such that a portion of the distal assembly (151, 156) extends distally beyond the distal end of the elongated shaft 141 (see fig. 20).

In regards to claim 60, Richardson et al. discloses a medical device wherein the ribbon or wire is a coiled ribbon or wire 151 (see fig. 20).

Richardson et al. disclose a guidewire comprising a plurality of polymer layers substantially arranged in the same manner as Applicant's device with the exception that Applicant has explicitly identified an inner polymer layer as "a tubular member" (see Applicant's drawings, figs. 3-4 and Richardson et al., figure 20; column 6/lines 1-24).

As such, Applying the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) and are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a guidewire similar to that of Richardson et al. with a plurality of polymer layers of different kinds arranged about the core wire and the coil since such a modification would serve the same purpose of enhancing the performance of the guidewire and providing a guidewire with a substantially constant outer transverse dimension which translates smoothly in an axial direction within catheter lumens, intracorporeal channels, or the like (see Richardson et al., column 19/lines 15-25 & 51-53; column 20/lines 15-20).

1) In figure 20, Richardson et al. disclose a guidewire embodiment comprising, inter alia, a tubular member wherein the distal end of the tubular member extends distally beyond the distal end of the core member;



It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a guidewire similar to that of Richardson et al.'s first embodiment with a coil that extends distally beyond the distal end of the tubular member similar to that of Richardson et al.'s second embodiment since such a

modification would serve the same purpose of fluoroscopically tracking and/or imaging the distal end of the guidewire (see Richardson et al., column 5/lines 39-60).

4. Claims 8, 11, 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richardson et al. (' 025) in view of Palmer et al. (US Patent No. 6,544,231).

Richardson et al. discloses a guidewire 10, as described above, that teaches all the limitations of the claims except Richardson et al. does not teach the process of laser welding or soldering. However, Palmer et al. disclose a medical instrument wherein a coil is bonded to a metallic tubular structure through laser welding (see column 4/lines 16-18). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a connected apparatus similar to that of Richardson et al. with a connecting process similar to that of Palmer et al. in order to tightly fuse metal elements together.

5. Claims 9-10 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richardson et al. (' 025) in view of Palmer et al. ('231) further in view of Cook et al. (US Patent No. 5,213,111).

Richardson et al. as modified by Palmer et al. discloses a guidewire, as described above, that teaches all the limitations of the claim except Richardson et al. as modified by Palmer et al. does not teach connecting the tubular member through crimping. However, Cook et al. disclose a guidewire wherein a coil member 151 is connected to a core member through crimping (see column 3/lines 13-16). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was

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made to provide a guidewire similar to that of Richardson et al. as modified by Palmer et al. with a connecting process similar to that of Cook et al. in order to hold the elements together in a friction-fit fashion.

6. Claims 1, 3-7, 12-15, 17, 21-22 and 59-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richardson et al. (US Patent No. 6,673,025) in view of Hodgson et al. (US 5,345,945).

In regards to claim 1, Richardson et al. discloses a guidewire 140, comprising:

a core member 141 having a proximal end and a distal end;

a tubular member 156 having a proximal end and a distal end, the tubular member 156 disposed about and connected to the distal end of the core member 141, the distal end of the tubular member 156 extending distally beyond the distal end of the core member 141; and

a coil member 151 connected to the tubular member 156 (see fig. 20).

In regards to claim 3, Richardson et al. discloses a guidewire wherein the proximal end of the coil member 151 is positioned distal of the distal end of the core member 141 (see fig. 20).

In regards to claim 4, Richardson et al. discloses a guidewire wherein the proximal end of the tubular member 156 fits over the distal end of the core member 141 (see fig. 20).

In regards to claim 5, Richardson et al. discloses a guidewire wherein the proximal end of the coil member fits over the distal end of the tubular member (see fig. 20).

In regards to claim 6, Richardson et al. discloses a guidewire further including a polymer sheath 157 disposed about the coil member 151, the tubular member 156, and at least a portion of the core member 141 (see fig. 20).

In regards to claim 7, Richardson et al. discloses a guidewire wherein the polymer sheath 157 is disposed over all of the core member 141 (see fig. 20).

In regards to claim 12, Richardson et al. discloses a guidewire wherein the tubular member 156 has a hemispherical cross section (see fig. 20).

In regards to claim 13, Richardson et al. discloses a guidewire wherein the tubular member 156 has a circular cross section (see fig. 20).

In regards to claim 14, Richardson et al. discloses a guidewire comprising:
a core member 141 including a proximal portion having a proximal end and a distal portion having a distal end; and

a distal assembly (151, 156) including a tubular member 156 having an inner surface adapted for connection to the distal portion of the core member 141, and an outer surface, and a coil member 151 connected to the tubular member 156;

wherein the distal assembly (151, 156) is connected to the distal portion of the core member 141 such that a portion of the distal assembly extends distally beyond the distal end of the core member 141 (see fig. 20).

In regards to claim 15, Richardson et al. discloses a guidewire wherein the distal assembly is connected to the distal portion of the core member 141 such that a portion of the tubular member 156 extends distally beyond the distal end of the core member 141 (see fig. 20).

In regards to claim 17, Richardson et al. discloses a guidewire further including a polymer sheath disposed about the coil member 151, the tubular member 156, and at least a portion of the core member 141 (see fig. 20).

In regards to claim 21, Richardson et al. discloses a guidewire wherein the tubular member 156 has a hemispherical cross section (see fig. 20).

In regards to claim 22, Richardson et al. discloses a guidewire wherein the tubular member 156 has a circular cross section (see fig. 20).

In regards to claim 59, Richardson et al. discloses a medical device comprising:
an elongated shaft 141 including a proximal portion having a proximal end and a distal portion having a distal end; and

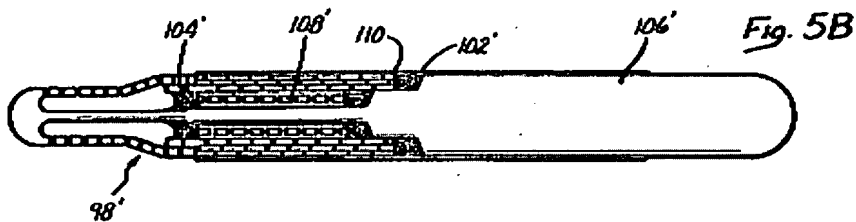
a distal assembly including a tubular member 156 and a ribbon or wire 151 connected to and extending distally of the tubular member 156; wherein the distal assembly is connected to the distal portion of the elongated shaft 141 such that a portion of the distal assembly (151, 156) extends distally beyond the distal end of the elongated shaft 141 (see fig. 20).

In regards to claim 60, Richardson et al. discloses a medical device wherein the ribbon or wire is a coiled ribbon or wire 151 (see fig. 20).

Richardson et al. disclose a guidewire comprising a plurality of polymer layers substantially arranged in the same manner as Applicant's device with the exception that Applicant has explicitly identified an inner polymer layer as "a tubular member" (see Applicant's drawings, figs. 3-4 and Richardson et al., figure 20; column 6/lines 1-24).

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Hodgson et al. disclose a guidewire wherein a coil 100 extends distally beyond the distal end of a tubular member; wherein the tubular member comprises a plurality of layered coils (see fig. 5B; column 5/lines 30-47).



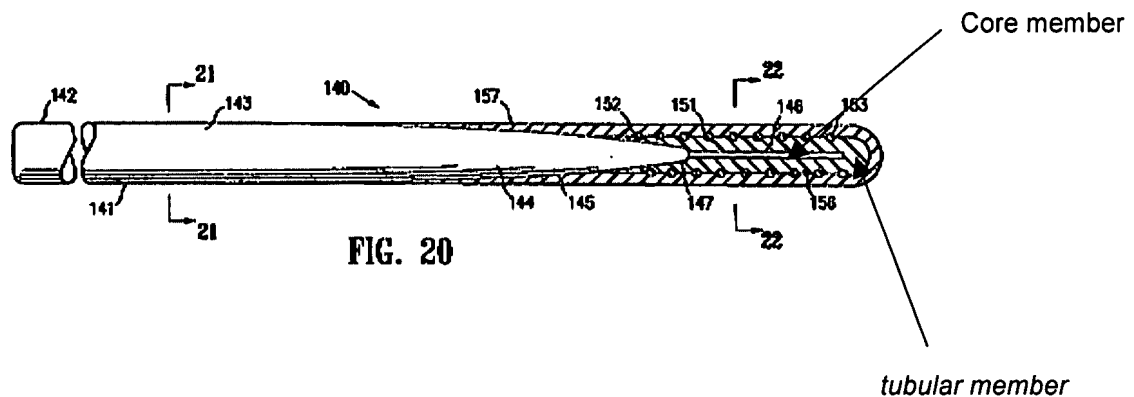
As such, Applying the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) and are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

It would have been obvious to one of ordinary skill in the art at the time

Applicant's invention was made to provide a guidewire similar to that of Richardson et al. with a plurality of polymer or coil layers of different kinds arranged about the core wire similar to that of Hodgson et al. since such a modification would serve the same purpose of enhancing the performance of the guidewire and providing a guidewire with a substantially constant outer transverse dimension which translates smoothly in an axial direction within catheter lumens, intracorporeal channels, or the like (see Richardson et al., column 19/lines 15-25 & 51-53; column 20/lines 15-20).

Moreover, in figure 20, Richardson et al. disclose a guidewire embodiment comprising, inter alia, a tubular member wherein the distal end of the tubular member extends distally beyond the distal end of the core member;



It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a guidewire similar to that of Richardson et al.'s first embodiment with a coil that extends distally beyond the distal end of the tubular member similar to that of Hodgson et al. since such a modification would serve the same purpose of fluoroscopically tracking and/or imaging the distal end of the guidewire (see Richardson et al., column 5/lines 39-60).

7. Claims 8, 11, 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richardson et al. ('025) in view of Hodgson et al. ('945) further in view of Palmer et al. (US Patent No. 6,544,231).

Richardson et al. as modified by Hodgson et al. discloses a guidewire 10, as described above, that teaches all the limitations of the claims except Richardson et al. as modified by Hodgson et al. does not teach the process of laser welding or soldering. However, Palmer et al. disclose a medical instrument wherein a coil is bonded to a

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metallic tubular structure through laser welding (see column 4/lines 16-18). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a connected apparatus similar to that of Richardson et al. as modified by Hodgson et al. with a connecting process similar to that of Palmer et al. in order to tightly fuse the metal elements together.

8. Claims 9-10 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richardson et al. ('025) in view of Hodgson et al. ('945) further in view of Palmer et al. ('231) even further in view of Cook et al. (US Patent No. 5,213,111).

Richardson et al. as modified by Hodgson et al. and Palmer et al. discloses a guidewire, as described above, that teaches all the limitations of the claim except Richardson et al. as modified by Hodgson et al. and Palmer et al. does not teach connecting the tubular member through crimping. However, Cook et al. disclose a guidewire wherein a coil member 151 is connected to a core member through crimping (see column 3/lines 13-16). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a guidewire similar to that of Richardson et al. as modified by Hodgson et al. and Palmer et al. with a connecting process similar to that of Cook et al. in order to hold the elements together in a friction-fit fashion.

Response to Arguments

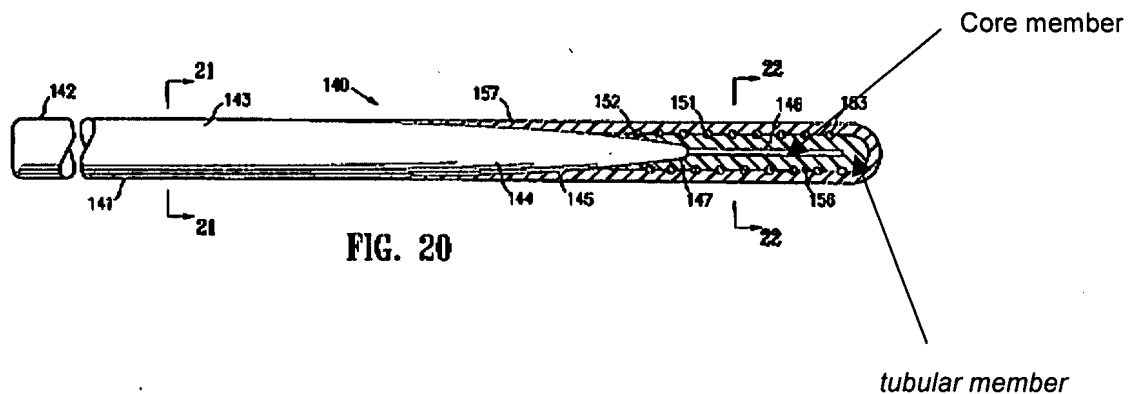
9. Applicant's arguments with respect to the Richardson reference have been fully considered but they are not persuasive. Applicant argues that Richardson does not teach a guidewire wherein the distal end of coil member extends distally beyond the

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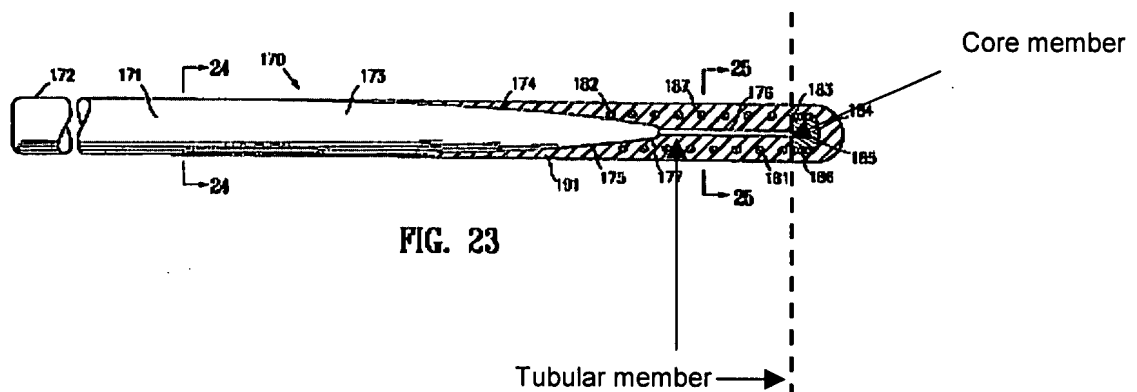
distal end of the tubular member. This argument has been considered and has not been deemed persuasive.

In regards to the Applicant's argument, the Examiner respectfully traverses. As noted in the rejections *supra*, Richardson et al. discloses several embodiments of the same invention as follows:

1) In figure 20, Richardson et al. disclose a guidewire embodiment comprising, inter alia, a tubular member wherein the distal end of the tubular member extends distally beyond the distal end of the core member;



2) In figures 23 and 32, Richardson et al. disclose a guidewire embodiment comprising, inter alia, a coil member (181, 183) wherein the coil member extends distally beyond the distal end of the tubular member;



It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a guidewire similar to that of Richardson et al.'s first embodiment with a coil that extends distally beyond the distal end of the tubular member similar to that of Richardson et al.'s second embodiment since such a modification would serve the same purpose of fluoroscopically tracking and/or imaging the distal end of the guidewire (see Richardson et al., column 5/lines 39-60). Moreover, the Applicant's specification has failed to disclose the critically of such a modification.

As such, the rejections under 103 over Richardson et al. in view of at least one of Palmer et al., and Cook et al. are maintained.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758.

The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/RTT/



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